

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings includes changes to Figures 3A-3F, 4, 5 and 6, to add Sequence Listing identifiers to amino acid sequences presented in the Figures. Please substitute the amended figures for the corresponding figures originally filed in the present application.

REMARKS

The Office Action of May 11, 2009 presents the examination of claims 1 and 3-21, claims 2 and 22-36 being withdrawn following restriction.

Amendment to the Sequence Listing and Specification

Enclosed herewith in full compliance with 37 C.F.R. §§1.821-1.825 is a Substitute Sequence Listing to be inserted into the specification as requested above. The Substitute Sequence Listing in no way introduces new matter into the specification.

The Substitute Sequence Listing is filed via EFS-Web as an electronic CRF copy. No paper copy is submitted.

The specification is amended to properly identify each sequence disclosed in the figures with a corresponding sequence identification number (SEQ ID NO). The Sequence Listing has been updated to identify the present application by filing date and serial number and to correct matters of form. In addition, the sequence of SEQ ID NOS: 12 through 16 have been added to the substitute Sequence Listing. SEQ ID NOS: 12 and 13 are depicted in Figure 3, SEQ ID NOS: 14 and 15 are shown in Figure 4, and SEQ ID NO: 16 is portrayed in Figures 5 and 6. No new matter is introduced by these amendments.

Amendments to the claims

The claims are amended to clarify their subject matter and to correct minor grammatical errors and other matters of form. Claim 37, directed to preferred embodiments, is added. No new matter is introduced by any amendment.

Replacement drawings

The Examiner has required insertion of Sequence Listing identifiers into Figures 3-6. Amended drawings complying with this requirement are attached.

Restriction requirement and objection to claims

The Examiner maintains the restriction requirement, asserting that it is proper in view of the different chemical nature of polynucleotides, polypeptides and antibodies that bind to the polypeptides.

The Examiner has not yet addressed Applicants' point, which is that the present application is a national stage of a PCT application, and thus the unity of invention rules for the PCT govern restriction practice in this application. Thus, the Examiner must first establish a novelty-breaking piece of prior art to show that the various embodiments of the invention the Examiner seeks to separate do not share a common technical feature. The Examiner has not yet provided such prior art.

The Examiner's willingness to rejoin claims to method of use of the polypeptide to make antibodies to the present application upon allowability of claims to the peptide per se is noted.

The Examiner objects to claims 1 and 3-21 as encompassing non-elected subject matter. The Examiner is not clear as to what subject matter is not properly within the claims. Applicants suppose that the objection relates to SEQ ID NO: 5, an alternative species to SEQ ID NO: 6, continuing to be recited in the claims.

Applicants submit that the Examiner improperly treats SEQ ID NO: 5 and SEQ ID NO: 6 as separate inventions. Both of these amino acid sequences represent immunodominant regions of a *Leishmania* antigen, and both have a common structure in being composed of repeat units of about 39 amino acids. Thus, SEQ ID NO: 5 and SEQ ID NO: 6 are distinct species within the generic claim 1 of the present application. As such, Applicants submit that it is proper for the present claims to recite both species, and if the subject matter of SEQ ID NO: 5 is found allowable, the Examiner should proceed to examine SEQ ID NO: 6 to determine if the generic claims are patentable.

Rejection under 35 USC § 112, second paragraph

Claims 1 and 3-21 are rejected under 35 USC § 112, second paragraph as being indefinite.

The Examiner rejects claim 1 because of its description of the claimed polypeptide "as recited in SEQ ID NO: 6". Claim 1 is amended in a manner that Applicants believe fully addresses this rejection.

The Examiner indicates that claim 1 is also unclear in the recitation that the polypeptide “contains one or more repeat regions of 39 amino acids. The Examiner explains that he does not see 39 amino acid long repeat units in the 155 amino acid sequence of SEQ ID NO: 5.

Figures 8 and 9 describe the “immunodominant repeat regions” and show them to be 39 amino acids long. Figure 7 shows a comparison of SEQ ID NO: 5 and SEQ ID NO: 6. SEQ ID NO: 5 (DDIMM in Figure 7) is 187 in length and SEQ ID NO: 6 (KEIMM in Figure 7) is 155 in length. The polypeptide SEQ ID NO: 6 having 155 amino acids has four immunodominant regions. The four repeats or immunodominant regions are amino acids at positions 1-38; 39-77; 78-116 and 117-155 of SEQ ID NO: 6. The first repeat is 38 amino acids in length whereas the other three repeats are 39 amino acids in length.

Similarly, Figure 5 is a comparison of the immunodominant region from *L. chagasi* with SEQ ID NO: 5 and SEQ ID NO: 6 of the present invention.

The description of 39 amino acid repeat within the sequence of SEQ ID NO: 5 and SEQ ID NO: 6 is further described at page 22, lines 3-6 and in the last paragraph on page 24. This text describes the immunodominant region for both the strains MHOM/IN/DD8 and MHOM/IN/KE16/1998. Further, Table 1 provides the comparison of the immunodominant regions from both of these strains with the immunodominant region from *L. chagasi*.

Accordingly, the structure of the claimed polypeptide is clear.

Claim 3 is deemed indefinite in reciting the phrase, “isolated from Indian strains of *Leishmania donovani*”. Claim 3 is amended to clarify that the polypeptide is one isolated from *L. donovani*, regardless of the country of origin.

The Examiner also seems to object to the scope of the claim as encompassing strains other than MHOM/IN/KE16/1998. Applicants submit that the claim is generic, but not unclear and therefore the instant rejection should be withdrawn.

Applicant believes the pending application is in condition for allowance. The favorable actions of withdrawal of the standing rejections, rejoinder of all of claims 2 and 22-37 to the application and allowance of claims 1-37 are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: September 11, 2009

Respectfully submitted,

By Mark J. Nuell
Mark J. Nuell
Registration No. 36,623
BIRCH, STEWART, KOLASCH & BIRCH, LLP
12770 High Bluff Drive, Suite 260
San Diego, California 92130
(858) 792-8855
Attorney for Applicant